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Indian Standard

POSITIVE LIST OF CONSTITUENTS OF ETHYLENE VINYL ACETATE (EVA) COPOLYMERS IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

UDC 678·742·2-134·442·2 : 663/644

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

August 1992

Price Group 2

Plastics Sectional Committee, PCD 12

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Plastics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

Plastics are now being used on a large scale for packaging of foodstuffs and pharmaceuticals. Where direct contact occurs between the packed commodity and the plastics, the high molecular mass polymer itself does not pose toxic hazards being inert and essentially insoluble in food. There is, however, a likelihood that some transfer may occur of polymer additives, adventitious impurities such as monomers, catalyst remnants and residual polymerisation solvents and of low molecular mass polymer fractions from the plastics into the packaged material with consequent toxic hazard to the consumers. The occurence of acute toxicity due to plastics materials in contact with food is most unlikely since only trace quantities of potentially toxic materials are likely to migrate. However, the accumulation of these toxic materials with time may lead to hazards which may be serious.

Ethylene vinyl acetate copolymers, commonly referred to as EVA copolymers or simply as EVA, may be produced to cover the complete range of comonomer ratios form 99 : 1 (ethylene : vinyl acetate) to 1 : 99. However, copolymers containing up to 50 percent vinyl acetate are classified as thermoplastics.

EVA copolymer is an inert material and offers good flexibility and toughness even at low temperature, low heat sealing temperature, excellent environmental stress crack resistance, etc.

EVA copolymers are particularly useful in the packaging industry. EVA copolymers may be injection moulded, blow moulded and extruded. EVA copolymers with vinyl acetate content up to 18 percent may also be converted into films by conventional processing methods such as blown, co-extrusion, cast, lamination and coating.

EVA copolymers may be combined with other polymers in co-extrusion for example, LDPE/EVA, HDPE/EVA, BOPP/EVA, Polyester/EVA, etc, giving improved performance in flexible packaging in the form of multilayer films which are widely used for food packaging.

EVA copolymers may also be blended with other polymers like LDPE, HDPE, PP, PVC, etc, to improve properties such as impact, flexiblity and easy heat sealablity.

This standard is intended to be used with the series of Indian Standards on plastics for food contact applications which is given in Annex A.

It is emphasized that these standards need to be used in combination to provide a system of control to the manufacturers of plastics as well as the fabricators of thermoplastics packaging materials to drive maximum benefits. Besides, it may also serve as basis for official agencies to frame suitable legislation to ensure effective safeguards for the safety and health of consumers where thermoplastics for food contact applications are concerned.

Indian Standard

POSITIVE LIST OF CONSTITUENTS OF ETHYLENE VINYL ACETATE (EVA) COPOLYMERS IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

1 SCOPE

1.1 This standard covers positive list of constituents of ethylene vinyl acetate (EVA) copolymers, namely, manufacturing residues and necessary additives which may be regarded as safe for use when properly processed in contact with foodstuffs, pharmaceuticals and drinking water and when present only in the prescribed limits of concentration.

1.2 It does not purport to establish the suitability of the ingredient singly in a particular foodstuff from other than toxicological consideration.

2 TERMINOLOGY

Ethylene Vinyl Acetate Copolymer (EVA)

A basic resin produced by the co-polymerisation of ethylene and vinyl acetate with a vinyl acetate content from 3 to 50 percent (*m/m*).

3 REQUIREMENTS

3.1 Basic Resin

3.1.1 A basic resin produced by the copolymerization of ethylene and vinyl acetate with a vinyl acetate content from 3 to 50 percent (*m/m*).

3.2 Manufacturing Residues

EVA copolymers may contain a total of not more than 0·2 percent by mass of ethylene and other hydrocarbons originating from ethylene feed stock, aldehydes, ketones and organic peroxides or their decomposition products.

3.2.1 *Emulsifying and Suspension Agents*

The total residues of emulsifying and suspension agents shall be not more than 0·3 percent by mass of the finished resin.

3.2.1.1 The residues of the following products may be present in EVA:

a) Alkyl, benzene, alkyl-benzene sulphates of sodium, potassium and ammonium, the alkyl group containing C_{10} to C_{20};

b) Alkyl, benzene, alkyl-benzene sulphonates of sodium, potassium and ammonium, the alkyl group containing C_{10} to C_{20};

c) Condensation products of ethylene oxide with monohydric aliphatic alcohols (C_{12} to C_{20}) and their sodium sulphates;

d) Condensation products of ethylene oxide with monobasic aliphatic acids (C_{12} to C_{20}) and their sodium and ammonium sulphates;

e) Condensation products of propylene oxide with monobasic aliphatic acids (C_{12} to C_{20}) and their sodium and ammonium sulphates; and

f) Polyvinyl alcohols (viscosity of a 4 percent aqueous solution at 20°C should be at least 4 centipoises).

3.2.2 *Catalyst*

The residues of the catalyst and their products of decomposition shall not exceed 0·2 percent by mass of the finished products. Where peroxide catalysts are used, the finished product shall not impart a positive reaction to the peroxides.

3.3 Polymerization Ingredients

Polymerization ingredients may be present provided that the manufacturer has obtained the specific approval of concerned authority within any limitations imposed by the authority.

3.4 Auxiliary Items for Working

3.4.1 *Lubricants*

The total lubricant content shall be not more than 2 percent of the finished resin except in those cases wherein it is specifically prescribed.

3.4.1.1 The following lubricants may be present in EVA copolymers:

a) Fatty acids, saturated or not;

b) Amides of fatty acids, saturated or not (*Max* 0·2 percent);

c) Aliphatic fatty alcohols higher than C_8;

d) N, N^t-bis-stearyl (and/or palmityl) ethylenediamine (*Max* 1 percent);

e) Microcrystalline waxes, paraffin or purified oil containing less than 0·1 ppm of noxious polycyclic aromatic hydrocarbons;

f) Esters of montanic acid with ethylene glycol and 1, 3 butylene butan diol;

g) Esters of diethylene glycol and oleic, palmitic, ricinoleic and stearic acids;

h) Monooleate, monopalmitate and monostearate of polyethylene glycol;

j) Oleates, palmitates and stearates of amyl, butyl, heptyl and octyl alcohols;

k) Octoates, oleate palmitate and stearate of zinc (*Max* 2 percent on the whole of these products);

m) Organo polysiloxanes with methyl and/or phenyl groups (silicone oil) the viscosity of which at 20°C is at least 100 centipoises;

n) Polyethylene glycol of molecular mass at least equal to 300 and the monoethylene glycol content of which is less than 0·1 percent;

p) Poly (1, 2-propylene-glycol) of molecular mass greater than 300 and the monoethylene glycol content of which is less than 0·1 percent;

q) Salts of zinc, calcium, sodium, aluminium, magnesium, ammonium and fatty acids, saturated and unsaturated monovalent;

r) Palmityl stearate;

s) Morpholine and its salts of fatty acids;

t) Calcium salts of phosphoric acids;

u) 2-hydroxyethyl-ester of amides of fatty acids;

v) Esters of glycerol with fatty acids, saturated or not;

w) Esters of sorbitol or sorbitan with the fatty acids, saturated or not; and

y) Phthalates of monovalent alcohols (C_8 to C_{20}) (*Max* 0·2 percent).

3.4.2 *Antioxidants*

The total antioxidant content shall not exceed 1·5 percent by mass of the finished resin.

3.4.2.1 EVA copolymers may have the following antioxidants added to them:

a) Thiodipropronic acid;

b) Di-cetyl-thio-dipropionate;

c) Dilauryl-thio-dipropionate;

d) Di-stearyl-thio-dipropionate;

e) Di-tert-butyl-paracresol;

f) 2-and/or 3-tert-butyl-4-hydroxyanisole (commoly known as BHA);

g) 4, 4′ butylidine-bis-(6-tert-butyl-m-cresol) (*Max* 0·3 percent);

h) 2, 6-di-tert-butyl-4-methoxy-methyl-phenol-zinc;

j) 4, 4′ methylene-bis-(2, 6-di-tert-butyl-phenol) (restricted);

k) n-octadecyl-(4′-hydroxy-3′, 5′-di-tert-butyl-phenyl) propionate;

m) 2-n-octyl-thio-4, 6-di (4-hydroxy-3′, 5′-di-tert-butyl) phenoxy triazine;

n) Thio-bis-di-sec-amyl phenol;

p) Thio-bis-(2 methyl-5-tert-butyl phenol);

q) 4, 4′-thio-bis-(6-tert-butyl-m-cresol) (*Max* 0·25 percent);

r) 2, 4, 5-trihydroxy butyrophenone;

s) 1, 3, 5-trimethyl-2, 4, 6-tris-(3, 5-di-tert-butyl-4-hydroxy-benzyl) benzene (*Max* 0·5 percent);

t) Tris (2-methyl-4-hydroxy-5-tert-butyl phenyl) butane;

u) 2, 4 dinonyl phenyl, di (4-mono-nonyl phenyl) phosphite with a maximum 20 percent content of di-*iso*-octyl, nonyl-phenyl phosphite and products of oxidation (*Max* 0 3 percent);

v) Phenol and/or cresol condensed with styrene and/or 1′-methyl styrene and/or olefins C_3 to C_{12};

w) Bis stearyl or palmityl ethylenediamine;

y) Propyl gallate;

z) Bis-[2-hydroxy-3-(methyl-cyclohexyl)-5-methy phenyl] methane;

aa) N, N′-di-(β-naphthyl)-p-penylene diamine; and

bb) Tetrakis [methylene-3 (3′ 5-ditertiary butyl 4′-hydroxy phenyl propionate)]-methane.

NOTE — Individual maximum, wherever stipulated above, shall be valid but the aggregate content of antioxidant shall be limited to 1·5 percent, *Max*.

3.4.3 *Antistatic and/or Antifogging Agent*

The material shall not contain antistatic and/or antifogging agents exceeding 0·5 percent by mass of the finished resin.

3.4.3.1 The following antistatic and/or antifogging agents may be permitted in ethylene vinyl acetate (EVA) copolymers:

a) Esters of diethanolamine and fatty acids C_6 and above;

b) Tri-*iso*-propanolamine (*Max* 0·5 percent);

c) N-N′-bis-(2-hydroxyethyl)-alkyl-(C_{12} to C_{18}) amines (*Max* 0·3 percent);

d) Products of condensation of ethylene oxide with a fatty acid C_{12} to C_{20}.

e) Cetyl pyridinium chloride (*Max* 0·4 percent);

f) Polyethylene-20-sorbitan monooleate; and

g) Sorbic acid, pure.

3.4.4 *Ultra-Violet Absorbers*

The total residues of ultra-violet absorbers in the finished resin shall not exceed 0·5 percent by mass.

3.4.4.1 The following ultra-violet absorbers may be present in EVA:

a) 2-carboxy-benzophenone;

b) 2, 2′-dihydroxybenzophenone;

c) 2-hydroxy-4-methoxybenzophenone;

d) 2, 2-dihydroxy-4-methoxybenzophenone;

e) 2-hydroxy-4-n-octoxybenzophenone (*Max* 0·2 percent);

f) Benzyl salicylate;

g) Phenyl salicylate;

h) Tert-butyl-phenyl salicylate (*Max* 0·5 percent);

j) 2-2′-hydroxy-5-methyl-phenyl benzotriazole;

k) 2-(2′-hydroxy-3 , 5′-di-tert-butyl phenol)-5-chlorobenzotriazole; and

m) 2-(2′-hydroxy-3′-tert-butyl-5-methyl phenyl)-5-chlorobenzotriazole (*Max* triazole content not to exceed 0·2 percent).

3.4.5 *Blowing Agents*

The following blowing agents may be present in EVA copolymers:

a) Adipic acid:

b) Succinic acid;

c) Carbonates of ammonium, potassium and sodium;

d) Citric acid;

e) Glutaric acid;

f) Laevulinic acid;

g) Lactic acid; and

h) Azo dicarbamide.

3.4.6 *Antifungal Agents*

Ascorbyl palmitate and stearate to a maximum of 1·0 percent by mass of the finished resin may be permitted as atifungal agents.

3.4.7 *Pigments, Fillers and Dyes*

The standard on permitted pigments, and colourants are listed is IS 9833 : 1981 'List of pigments and colourants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water'.

3.4.8 *Other Additives Including Anti-blocking Agent for EVA Copolymers*

The other permitted additives are as follows:

a) Oxides of aluminium, magnesium, silicon, titanium and zinc (1 percent *Max* zinc in the metallic state);

b) Silicates of aluminium, calcium, magnesium, potassium and sodium including asbestos; and

c) Carbon black 3 percent, *Max*.

ANNEX A

(*Foreword*)

LIST OF INDIAN STANDARDS ON PLASTICS FOR FOOD CONTACT APPLICATIONS

IS No.	*Title*
9833 : 1981	List of pigments and colourants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water
9845 : 1986	Method of analysis for the determination of specific and/or overall migrations of constituents of plastic materials and articles intended to come into contact with foodstuffs (*first revision*)
10141 : 1982	Positive list of constituents of polyethylene in contact with foodstuffs, pharmaceuticals and drinking water

IS No.	*Title*
10142 : 1982	Specification for styrene polymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
10146 : 1982	Specification for polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
10148 : 1982	Positive list of constituents of polyvinyl chloride (PVC) and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water
10149 : 1982	Positive list of constituents of styrene polymers in contact with foodstuffs, pharmaceuticals and drinking water
10151 : 1982	Specification for polyvinyl chloride (PVC) and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
10171 : 1987	Guide on suitability of plastics for food packaging (*first revision*)
10909 : 1984	Positive list of constituents of polypropylene in contact with foodstuffs, pharmaceuticals and drinking water
10910 : 1984	Specification for polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11434 : 1985	Specification for ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11435 : 1985	Positive list of constituents of ionomer resin for safe use in contact with foodstuffs, pharmaceuticals and drinking water
11704 : 1986	Specification for ethylene/acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs pharmaceuticals and drinking water
11705 : 1986	Positive list of constituents of ethylene/acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
12229 : 1987	Positive list of constituents of polyalkylene terephathalates (PET and PBT) for their safe use in contact with foodstuffs, pharmaceutical and drinking water
12247 : 1988	Specification for Nylon 6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
12248 : 1988	Positive list of constituents of Nylon 6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
12252 : 1987	Specification for polyalkylene Terephthlalates (PET and PBT) for their safe use in their safe use in contact with foodstuffs, pharmaceuticals and drinking water

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Doc : No. PCD 12 (906)

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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Printed at New India Printing Press, Khurja, India